

approved supplement NDA 19-771/S-018.” Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions regarding this application, please call Babette Merritt, Project Manager, at (301) 827-2222.

Sincerely,

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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cc:

Archival NDA 19-771

HFD-560/Div. Files

HFD-560/B.Merritt (with copy of labeling)

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HFD-830/DNDC Division Director

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APPROVAL (AP)